UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,805	12/13/2006	Martin Dugas	22329-US	3903

22829 7590 10/31/2007
ROCHE MOLECULAR SYSTEMS INC
PATENT LAW DEPARTMENT
1145 ATLANTIC AVENUE
ALAMEDA, CA 94501

EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,805	DUGAS ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16, drawn to a method for distinguishing t(11q23)/MLL-positive leukemias from t(11q23)MLL negative leukemias.

Group II, claim(s) 17-18, drawn to use of at least one marker for the manufacturing of a diagnostic for distinguishing t(11q23)/MLL-positive leukemias from t(11q23)MLL negative leukemias.

Group III, claim(s) 19-27, drawn to a diagnostic kit containing at least one marker for distinguishing t(11q23)/MLL-positive leukemias from t(11q23)MLL negative leukemias and a reference data bank for distinguishing t(11q23)/MLL-positive leukemias from t(11q23)MLL negative leukemias.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

It appears that the technical feature linking groups I-III is that they all relate to reagents for detecting markers for distinguishing t(11q23)/MLL-positive leukemias from t(11q23)MLL negative leukemias.

However, Shen-Ong et al (Cancer Research, June 2003, 63:3296-3301), as evidenced by the instant specification, teaches reagents for detecting markers for distinguishing t(11q23)/MLL-positive leukemias from t(11q23)MLL negative leukemias (see the kit Affymetrix U133 kit used by Shen-Ong et al at page 3296, as evidenced by the Affymetrix U133 kit disclosed on page 8 of the instant specification).

Therefore, the technical feature linking the inventions of groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, groups I-III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 1-16 are generic to a plurality of disclosed patentably distinct species of "**methods for distinguishing t(11q23)/MLL-positive leukemias from t(11q23)MLL negative leukemias**" comprising methods of determining the expression of distinct makers (marker number and whether marker is to be measured in the form of a polynucleotide or polypeptide) wherein a distinct expression pattern (whether higher or lower expression is to be detected for each marker) indicative of a distinct result (see claim 1). It is further noted that these species are related as combination and subcombination. In the instant case, each combination does not necessarily share unity with any one subcombination as clearly evidenced by the plural subcombinations claimed. The following are examples of species of methods for distinguishing t(11q23)/MLL-positive leukemias from t(11q23)MLL negative leukemias: a method of determining the expression of polynucleotides in the form of a polypeptide defined by Affymetrix Identification Numbers 1 and 2 wherein a lower expression of a polynucleotide in the form of a polypeptide defined by Affymetrix Identification Number 1 and a higher expression of a polynucleotide in the form of a polypeptide defined by

Affymetrix Identification Number 2 is indicative for the presence of denovo AML when denovo AML is distinguished from therapy-related AML; a method of determining the expression of polynucleotides in the form of a polynucleotide defined by Affymetrix Identification Numbers 1 and 2 wherein a lower expression of a polynucleotide in the form of a polynucleotide defined by Affymetrix Identification Number 1 and a higher expression of a polynucleotide in the form of a polynucleotide defined by Affymetrix Identification Number 2 is indicative for the presence of denovo AML when denovo AML is distinguished from therapy-related AML; and a method of determining the expression of polynucleotides in the form of a polypeptide defined by Affymetrix Identification Numbers 1, 2, 4, and 5 wherein a lower expression of polynucleotides in the form of polypeptides defined by Affymetrix Identification Numbers 1 and 4 and higher expression of polynucleotides in the form of a polypeptides defined by Affymetrix Identification Numbers 2 and 5 are indicative for the presence of denovo AML when denovo AML is distinguished from therapy-related AML). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The methods of the above species differ at least in objectives, method steps, reagents used, response variables, and criteria for success such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 17-18 are generic to a plurality of disclosed patentably distinct species of "**uses of makers for manufacturing of a diagnostic**" comprising uses of specific combination of markers. It is further noted that these species are related as combination and subcombination. In the instant case, each combination does not necessarily share unity with any one subcombination as clearly evidenced by the plural subcombinations claimed. The following are examples of species of uses of markers for manufacturing of a diagnostic: use of markers identifiable by Affymetrix Identification Numbers 1 and 2; use of markers identifiable by Affymetrix Identification Numbers 3 and 4; use of markers identifiable by Affymetrix Identification Numbers 1, 2, 3, and 4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The methods of the above species differ at least in objectives, method steps, reagents and criteria for success such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 19-21 are generic to a plurality of disclosed patentably distinct species of "**diagnostic kits containing at least one marker for distinguishing t(11q23)/MLL-positive leukemias from t(11q23)MLL negative leukemias**" comprising specific combinations of markers. It is further noted that these species are related as combination and subcombination. In the instant case, each combination does not necessarily share unity with any one subcombination as clearly evidenced by the plural subcombinations claimed. The following are examples of species of diagnostic kits containing at least one marker for distinguishing t(11q23)/MLL-positive leukemias from t(11q23)MLL negative leukemias comprising specific combinations of markers: diagnostic kits containing markers identifiable by Affymetrix Identification Numbers 1 and 2; diagnostic kits containing markers identifiable by Affymetrix Identification Numbers 3 and 4; diagnostic kits containing markers identifiable by Affymetrix Identification Numbers 5, 14, and 18. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 19-27 are generic to a plurality of disclosed patentably distinct species of "**data banks**" comprising profiles based on specific combinations of markers. It is further noted that these species are related as combination and subcombination. In the instant case, each combination does not necessarily share unity with any one subcombination as clearly evidenced by the plural subcombinations claimed. The following are examples of species of data banks encompassed by the claims: data banks based on expression of markers identifiable by Affymetrix Identification Numbers 3 and 4; data banks based on expression of markers identifiable by Affymetrix Identification Numbers 1 and 2; data banks based on expression of markers identifiable by Affymetrix Identification Numbers 3. 4. 26, and 29. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added.

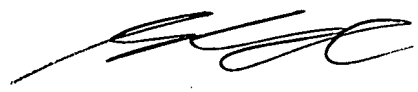
An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SEA